K123616

DEC 2 1 2012

Tab 4 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number: _____

Date of submission: November 15, 2012

Submitter:

SonoScape Company Limited

Address: 4F, Yizhe Building, Yuquan Road,Nanshan, Shenzhen 518051, P.R.China

Tel: (86) 755-26722890

Fax: (86) 755-26722850

Contact Person: Zhou Wenping

Submission Correspondent:

Ms. Diana Hong & Mr. Lee Fu

Mid-Link Consulting Co., Ltd

P.O. Box 237-023, Shanghai, 200237, China

Tel: +86-21-22815850

Fax: 240-238-7587

Email: info@mid-link.net

Proposed Device Identification:

*** Trade/Proprietary Name:**
A6 Portable Ultrasonic Diagnostic System

*** Common Name:** Diagnostic Ultrasound System and Transducers

*** Classification:**

Regulatory Class: II

21 CFR 892.1560 Ultrasonic Pulsed Echo Imaging System(90-IYO)

21 CFR 892.1570 Diagnostic Ultrasound Transducer(90-ITX)

Legally Marketed Predicate Device:

SonoScape A6 Portable Ultrasonic Diagnostic System
510(k) Number: K101337

Description:

The A6 Portable Ultrasonic Diagnostic System with added transducer is a general purpose, portable, software controlled and ultrasound diagnostic system. This ultrasonic device is designed to project ultrasound waves into body tissue and to present the returned echo information on the monitor. The resulting information is displayed in B-Mode, M-Mode and THI- Mode or in the combined mode (i.e. B/M-Mode). This system is a Track I device that employs an array of probes that include linear array and convex linear array with a frequency range of approximately 2.0 MHz to 12 MHz.

Intended Use Statement:

The A6 Portable Ultrasonic Diagnostic System with added transducer is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen, Cardiac, Small Organ (Thyroid, parathyroid, parotid, submaxillary gland, testes and breast.), Peripheral Vascular, Transvaginal, Transrectal, Musculo-skeletal (Conventional and Superficial), Pediatric, Fetal, OB/Gyn and Urology. This device is intended to adult, pregnant woman, pediatric, and neonate.

Technological Characteristics:

The A6 Portable Ultrasonic Diagnostic System with added transducer incorporates the same fundamental technology as the predicate device. The device has been tested as Track 1 Device per the FDA Guidance document "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued September 9, 2008. The acoustic output is measured and calculated per NEMA UD 2 Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment: 2004. All transducers used with the A6 Portable Ultrasonic Diagnostic System are track 1. All patient contact materials

are biocompatible. The technology characteristics of the A6 Portable Ultrasonic Diagnostic System with these modifications do not affect the safety or efficacy of the device.

Testing:

Laboratory testing was conducted to verify that the A6 Portable Ultrasonic Diagnostic System with added transducer met all design specification and was substantially equivalent to the Predicate Device. The device has been found to conform to applicable medical device safety standards in regards to thermal, mechanical and electrical safety as well as biocompatibility. Acoustic output is measured and calculated according to "Acoustic Output Measuring Standard for Diagnostic Ultrasound Equipment".

IEC 60601-1: 2005 Medical Electrical Equipment - Part 1: General Requirements for Safety

IEC 60601-1-2: 2007 Medical Electrical Equipment - Part 1-2: General Requirements for Safety - Collateral Standard: Electromagnetic Compatibility -- Requirements and Tests.

IEC 60601-2-37: 2008 Medical electrical equipment - Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment.

NEMA UD 2-2004, Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment Version 3.

Clinical Test:

No clinical testing was required.

Substantially Equivalent Conclusion

The proposed device, A6 Portable Ultrasonic Diagnostic System, is determined to be Substantially Equivalent (SE) to the predicate device in respect of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

SonoScape Company Limited
% Ms. Diana Hong & Mr. Lee Fu
General Manager
Mid-Link Consulting Co., Ltd.
P.O. Box 237-023, Shanghai, 200237
CHINA

DEC 2 1 2012

Re: K123616
Trade/Device Name: Portable Ultrasonic Diagnostic System
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO and ITX
Dated: November 23, 2012
Received: November 23, 2012

Dear Ms. Hong:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Portable Ultrasonic Diagnostic System, as described in your premarket notification:

Transducer Model Number

6V4 Micro-curved Array
6V5 Micro-curved Array
EC2 Micro-curved Array
BCC9-4 Micro-curved Array
C612 Micro-curved Array
C312 Micro-curved Array
C351 Curved Array
C352 Curved Array
C543 Curved Array
L745 Linear Array
L746 Linear Array

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure(s)

Tab 2 Indications for Use

510(k) Number: K123616

Device Name: Portable Ultrasonic Diagnostic System

Indications for Use:

The A6 Portable Ultrasonic Diagnostic System with added transducer is a general-purpose ultrasonic imaging instrument intended for use by a qualified physician for evaluation of Abdomen, Cardiac, Small Organ (Thyroid, parathyroid, parotid, submaxillar, gland, testes and breast.), Peripheral Vascular, Trans-vaginal, Trans-rectal, Musculo-skeletal (Conventional and Superficial), Pediatric, Fetal, OB/Gyn and Urology. This device is intended to adult, pregnant woman, pediatric, and neonate.

Prescription Use _____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

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Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

510(k) K123616

Diagnostic Ultrasound Indications for Use Form

System: **SonoScape A6**
Diagnostic Ultrasound Pulsed Echo System

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal	P	P					Note 1	Note 2
	Abdominal	P	P					Note 1	Note 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	P	P					Note 1	Note 2
	Small Organ (specify)	P	P					Note 1	Note 2,3
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P					Note 1	Note 2
	Trans-vaginal	P	P					Note 1	Note 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)	P	P					Note 1	Note 2
	Musculo-skeletal (Superficial)	P	P					Note 1	Note 2
	Intravascular								
	Other (Urology)	P	P					Note 1	Note 2
	Other (Ob/GYN)	P	P					Note 1	Note 2
Cardiac	Cardiac Adult	P	P					Note 1	Note 2
	Cardiac Pediatric	P	P					Note 1	Note 2
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	P	P					Note 1	Note 2
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B/M
Note 2: THI (Tissue Harmonic Imaging). The feature does not use contrast agents.
Note 3: Small Organ (Thyroid, parathyroid, parotid, submaxillary gland, testes and breast.)

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510(k) K126616

Diagnostic Ultrasound Indications for Use Form

Transducer: **6V4 Micro-curved Array**
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	**Specific (TRACKS 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Other* Combined**	**Other* Specify**
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal	P	P					Note 1	Note 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal **(Conventional)**								
	Musculo-skeletal **(Superficial)**								
	Intravascular								
	Other (Urology)								
	Other (Ob/GYN)	P	P					Note 1	Note 2
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B/M

Note 2: THI (Tissue Harmonic Imaging). The feature does not use contrast agents.

Note 3: Small Organ (Thyroid, parathyroid, parotid, submaxillary gland, testes and breast.)

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510(k) K123616

Diagnostic Ultrasound Indications for Use Form

Transducer: **6V5 Micro-curved Array**
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	**Specific (TRACKS 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Other* Combined**	**Other* Specify**
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P					Note 1	Note 2
	Trans-vaginal	P	P					Note 1	Note 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (**Conventional**)								
	Musculo-skeletal (**Superficial**)								
	Intravascular								
	Other (Urology)	P	P					Note 1	Note 2
	Other (Ob/GYN)	P	P					Note 1	Note 2
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B/M

Note 2: THI (Tissue Harmonic Imaging). The feature does not use contrast agents.

Note 3: Small Organ (Thyroid, parathyroid, parotid, submaxillary gland, testes and breast.)

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510(k) K123616

Diagnostic Ultrasound Indications for Use Form

Transducer: **EC2 Micro-curved Array**
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	**Specific (TRACKS 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Other* Combined**	**Other* Specify**
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P					Note 1	Note 2
	Trans-vaginal	P	P					Note 1	Note 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal **(Conventional)**								
	Musculo-skeletal **(Superficial)**								
	Intravascular								
	Other (Urology)	P	P					Note 1	Note 2
	Other (Ob/GYN)	P	P					Note 1	Note 2
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B/M

Note 2: THI (Tissue Harmonic Imaging). The feature does not use contrast agents.

Note 3: Small Organ (Thyroid, parathyroid, parotid, submaxillary gland, testes and breast.)

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Diagnostic Ultrasound Indications for Use Form

Transducer: **BCC9-4 Micro-curved Array**
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal	P	P					Note 1	Note 2
	Trans-vaginal	P	P					Note 1	Note 2
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (Conventional)								
	Musculo-skeletal (Superficial)								
	Intravascular								
	Other (Urology)	P	P					Note 1	Note 2
	Other (Ob/GYN)	P	P					Note 1	Note 2
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B/M

Note 2: THI (Tissue Harmonic Imaging). The feature does not use contrast agents.

Note 3: Small Organ (Thyroid, parathyroid, parotid, submaxillary gland, testes and breast.)

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510(k) K123616

Diagnostic Ultrasound Indications for Use Form

Transducer: **C612 Micro-curved Array**
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal	P	P					Note 1	Note 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	P	P					Note 1	Note 2
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (**Conventional**)								
	Musculo-skeletal (**Superficial**)								
	Intravascular								
	Other (Urology)								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric	P	P					Note 1	Note 2
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B/M

Note 2: THI (Tissue Harmonic Imaging). The feature does not use contrast agents.

Note 3: Small Organ (Thyroid, parathyroid, parotid, submaxillary gland, testes and breast.)

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510(k) K123616

Diagnostic Ultrasound Indications for Use Form

Transducer: **C312 Micro-curved Array**
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	**Specific (TRACKS 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Other* Combined**	**Other* Specify**
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal **(Conventional)**								
	Musculo-skeletal **(Superficial)**								
	Intravascular								
	Other (Urology)								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult	P	P					Note 1	Note 2
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B/M

Note 2: THI (Tissue Harmonic Imaging). The feature does not use contrast agents.

Note 3: Small Organ (Thyroid, parathyroid, parotid, submaxillary gland, testes and breast.)

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510(k) K123616

Diagnostic Ultrasound Indications for Use Form

Transducer: **C351 Curved Array**
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	**Specific (TRACKS 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Other* Combined**	**Other* Specify**
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal	P	P					Note 1	Note 2
	Abdominal	P	P					Note 1	Note 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal **(Conventional)**								
	Musculo-skeletal **(Superficial)**								
	Intravascular								
	Other (Urology)	P	P					Note 1	Note 2
	Other (Ob/GYN)	P	P					Note 1	Note 2
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B/M

Note 2: THI (Tissue Harmonic Imaging). The feature does not use contrast agents.

Note 3: Small Organ (Thyroid, parathyroid, parotid, submaxillary gland, testes and breast.)

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510(k) K123616

Diagnostic Ultrasound Indications for Use Form

Transducer: **C352 Curved Array**
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	Specific (TRACKS 1 & 3)	B	M	PWD	CWD	Color Doppler	Power (Amplitude) Doppler	Other* Combined	Other* Specify
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal	P	P					Note 1	Note 2
	Abdominal	P	P					Note 1	Note 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal (**Conventional**)								
	Musculo-skeletal (**Superficial**)								
	Intravascular								
	Other (Urology)	P	P					Note 1	Note 2
	Other (Ob/GYN)	P	P					Note 1	Note 2
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B/M

Note 2: THI (Tissue Harmonic Imaging). The feature does not use contrast agents.

Note 3: Small Organ (Thyroid, parathyroid, parotid, submaxillary gland, testes and breast.)

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Office of In Vitro Diagnostics and Radiological Health

510(k) K123616

Diagnostic Ultrasound Indications for Use Form

Transducer: **C543 Curved Array**
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	**Specific (TRACKS 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Other* Combined**	**Other* Specify**
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal	P	P					Note 1	Note 2
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric	P	P					Note 1	Note 2
	Small Organ (specify)								
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal **(Conventional)**								
	Musculo-skeletal **(Superficial)**								
	Intravascular								
	Other (Urology)								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel								
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B/M

Note 2: THI (Tissue Harmonic Imaging). The feature does not use contrast agents.

Note 3: Small Organ (Thyroid, parathyroid, parotid, submaxillary gland, testes and breast.)

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510(k) K123616

Diagnostic Ultrasound Indications for Use Form

Transducer: **L745 Linear Array**
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	**Specific (TRACKS 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Other* Combined**	**Other* Specify**
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	P	P					Note 1	Note 2,3
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal **(Conventional)**	P	P					Note 1	Note 2
	Musculo-skeletal **(Superficial)**	P	P					Note 1	Note 2
	Intravascular								
	Other (Urology)								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	P	P					Note 1	Note 2
	Other (specify)								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Note 1: B/M

Note 2: THI (Tissue Harmonic Imaging). The feature does not use contrast agents.

Note 3: Small Organ (Thyroid, parathyroid, parotid, submaxillary gland, testes and breast.)

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Division of Radiological Health
Office of In Vitro Diagnostics and Radiological Health
510(k) K123616

Diagnostic Ultrasound Indications for Use Form

Transducer: **L746 Linear Array**
Diagnostic Ultrasound Transducer

Intended Use: Diagnostic ultrasound imaging or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation							
General (TRACK 1 ONLY)	**Specific (TRACKS 1 & 3)**	**B**	**M**	**PWD**	**CWD**	**Color Doppler**	**Power (Amplitude) Doppler**	**Other* Combined**	**Other* Specify**
Ophthalmic	Ophthalmic								
Fetal Imaging& Other	Fetal								
	Abdominal								
	Intra-operative Specify								
	Intra-operative Neuro								
	Laparoscopic								
	Pediatric								
	Small Organ (specify)	P	P					Note 1	Note 2,3
	Neonatal Cephalic								
	Adult Cephalic								
	Trans-rectal								
	Trans-vaginal								
	Trans-urethral								
	Trans-esoph.(non-Card)								
	Musculo-skeletal **(Conventional)**	P	P					Note 1	Note 2
	Musculo-skeletal **(Superficial)**	P	P					Note 1	Note 2
	Intravascular								
	Other (Urology)								
	Other (Ob/GYN)								
Cardiac	Cardiac Adult								
	Cardiac Pediatric								
	Intravascular(Cardiac)								
	Trans-esoph.(Cardiac)								
	Intra-cardiac								
	Other (specify)								
Peripheral Vessel	Peripheral vessel	P	P					Note 1	Note 2
	Other (specify)								

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